



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the substantiation of health claims related to various microorganisms and changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), and stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2012.2857](https://doi.org/10.2903/j.efsa.2012.2857)

Publication date:
2012

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2012). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the substantiation of health claims related to various microorganisms and changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), and stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006*. European Food Safety Authority. the EFSA Journal Vol. 10(8) No. 2857 <https://doi.org/10.2903/j.efsa.2012.2857>

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various microorganisms and changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), and stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment related to various microorganisms and changes in bowel function, and digestion and absorption of nutrients, decreasing potentially pathogenic gastro-intestinal microorganisms, and stimulation of immunological responses. The food constituents, *Bifidobacterium animalis* subsp. *lactis* THT 010801, *Bifidobacterium longum* subsp. *infantis* THT 010201, *Bifidobacterium longum* subsp. *longum* THT 010301, *Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501, *Lactobacillus casei* THT 030401, *Lactobacillus gasseri* THT 031301, *Lactobacillus helveticus* THT 031102, *Lactobacillus plantarum* THT 030701, *Lactobacillus plantarum* THT 030707, *Lactobacillus reuteri* THT 030802, *Lactobacillus salivarius* THT 031001 and *Streptococcus thermophilus* THT 070102, are sufficiently characterised. The evidence provided did not establish that the proposed claimed effect, stimulation of immunological responses, is a beneficial physiological effect. The references provided for the health claims related to changes in bowel function and decreasing potentially pathogenic gastro-intestinal microorganisms included studies which assessed the effects of food constituents other than the food constituents which are the

¹ On request from the European Commission, Question No EFSA-Q-2012-00133, EFSA-Q-2012-00134, EFSA-Q-2012-00135, EFSA-Q-2012-00136, EFSA-Q-2012-00137, EFSA-Q-2012-00138, EFSA-Q-2012-00139, EFSA-Q-2012-00140, EFSA-Q-2012-00141, EFSA-Q-2012-00142, EFSA-Q-2012-00143, EFSA-Q-2012-00144, EFSA-Q-2012-00145, EFSA-Q-2012-00146, EFSA-Q-2012-00147, EFSA-Q-2012-00148, EFSA-Q-2012-00149, EFSA-Q-2012-00150, EFSA-Q-2012-00151, EFSA-Q-2012-00152, EFSA-Q-2012-00153, EFSA-Q-2012-00154, EFSA-Q-2012-00155, EFSA-Q-2012-00158, EFSA-Q-2012-00159, adopted on 28 June 2012.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the substantiation of health claims related to various microorganisms and changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014), and stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(8):2857. [32 pp.]. doi:10.2903/j.efsa.2012.2857. Available online: www.efsa.europa.eu/efsajournal

subject of the claims and/or investigated health outcomes unrelated to the claimed effects. No human studies which investigated the effects of the food constituents on appropriate measures of the claimed effects were provided. On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents and the claimed effects evaluated in this opinion.

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KEY WORDS

Bifidobacterium animalis subsp. *lactis* THT 010801, *Bifidobacterium longum* subsp. *infantis* THT 010201, *Bifidobacterium longum* subsp. *longum* THT 010301, *Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501, *Lactobacillus casei* THT 030401, *Lactobacillus gasseri* THT 031301, *Lactobacillus helveticus* THT 031102, *Lactobacillus plantarum* THT 030701, *Lactobacillus plantarum* THT 030707, *Lactobacillus reuteri* THT 030802, *Lactobacillus salivarius* THT 031001, *Streptococcus thermophilus* THT 070102, health claims.

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of health claims in relation to various microorganisms and changes in bowel function, and digestion and absorption of nutrients, decreasing potentially pathogenic gastro-intestinal microorganisms, and stimulation of immunological responses. The scientific substantiation is based on the information provided by the competent Authority of Belgium for further assessment of these claims.

The following food constituents are sufficiently characterised:

Bifidobacterium animalis subsp. *lactis* THT 010801 (ID 960, 961, 962),

Bifidobacterium longum subsp. *infantis* THT 010201 (ID 967, 968),

Bifidobacterium longum subsp. *longum* THT 010301 (ID 969, 970),

Bifidobacterium pseudolongum subsp. *pseudolongum* THT 010501 (ID 971, 972),

Lactobacillus casei THT 030401 (ID 975, 976),

Lactobacillus gasseri THT 031301 (ID 983, 984),

Lactobacillus helveticus THT 031102 (ID 985, 986),

Lactobacillus plantarum THT 030701 (ID 994, 995),

Lactobacillus plantarum THT 030707 (ID 996, 997),

Lactobacillus reuteri THT 030802 (ID 998, 999),

Lactobacillus salivarius THT 031001 (ID 1006, 1007),

Streptococcus thermophilus THT 070102 (ID 1014, 1015).

Changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

The claimed effects, which are proposed for further assessment, relate to “contribute to the secretion and absorption of nutrients”, “degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids”, “they participate in mobility intestinal” and “improve the intestinal transit”. The claimed effect “contribute to the secretion and absorption of nutrients” is not sufficiently defined and it was not possible to establish for which nutrients an improved digestion and absorption is claimed. The claimed effect “degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids” is assumed to refer to changes in short chain fatty acid (SCFA) and lactic acid production. Changes in SCFA and lactic acid production in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. The claimed effects “they participate in mobility intestinal” and “improve the intestinal transit” are assumed to refer to changes in bowel function. Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and changes in bowel function.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

The claimed effect, which is proposed for further assessment, relates to a decrease in potentially pathogenic gastro-intestinal microorganisms. The proposed target population is the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and decreasing potentially pathogenic gastro-intestinal microorganisms.

Stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015)

The claimed effect, which is proposed for further assessment, relates to the stimulation of various immunological responses. The proposed target population is the general population. The Panel notes that stimulation of immunological responses is not a beneficial physiological effect *per se*, but needs to be linked to a beneficial physiological or clinical outcome.

The Panel considers that the evidence provided did not establish that stimulation of immunological responses is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents, which are the subject of the claims, and a beneficial physiological effect related to stimulation of immunological responses.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ in which the Panel concluded that the data available were not sufficient to characterise *Bifidobacterium animalis* subsp. *lactis* THT 010801 (ID 960, 961, 962), *Bifidobacterium longum* subsp. *infantis* THT 010201 (ID 967, 968), *Bifidobacterium longum* THT 010301 (ID 969, 970), *Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501 (ID 971, 972), *Lactobacillus casei* THT 030401 (ID 975, 976), *Lactobacillus gasseri* THT 031301 (ID 983, 984), *Lactobacillus helveticus* THT 031102 (ID 985, 986), *Lactobacillus plantarum* THT 030701 (ID 994, 995), *Lactobacillus plantarum* THT 030707 (ID 996, 997), *Lactobacillus reuteri* THT 030802 (ID 998, 999), *Lactobacillus salivarius* THT 031001 (ID 1006, 1007) and *Streptococcus thermophilus* THT 070102 (ID 1014, 1015) (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009), EFSA received additional information from the competent Authority of Belgium for the further assessment of this claim. The information provided in the framework of the further assessment for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

1.1. *Bifidobacterium animalis* subsp. *lactis* THT 010801 (ID 960, 961, 962)

The food constituent that is the subject of the proposed health claims is *Bifidobacterium animalis* subsp. *lactis* THT 010801.

The strain *B. animalis* subsp. *lactis* THT 010801 is the trade name for *B. animalis* subsp. *lactis* LMG 18314, which is the type strain of *B. animalis* subsp. *lactis*. Culture collection numbers from different internationally recognised culture collections (e.g. LMG 18314, DSM 10140) were provided. Data on the identification and characterisation of *B. animalis* subsp. *lactis* THT 010801 at species and strain level, by using different phenotypic (carbohydrate fermentation pattern, PAGE) and genotypic (DNA-DNA hybridisation, 16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, plasmidic profile, species-specific PCR, ARDRA, Rep-PCR, AFLP, ribotyping, MLST, RAPD and PFGE) methods, were provided (Alander et al., 2001; Crittenden et al., 2001; Duez et al., 2000; Masco et al., 2004; Matto et al., 2004; Roy and Sirois, 2000; Ventura and Zink, 2002; Ventura et al., 2006).

The Panel considers that the food constituent that is the subject of the proposed health claims, *B. animalis* subsp. *lactis* THT 010801, is sufficiently characterised.

1.2. *Bifidobacterium longum* subsp. *infantis* THT 010201 (ID 967, 968)

The food constituent that is the subject of the proposed health claims is *Bifidobacterium longum* subsp. *infantis* THT 010201.

For *B. longum* subsp. *infantis* THT 010201, a culture collection number from the Belgian Co-ordinated Collections of Microorganisms (LMG 25627) was provided. The BCCM/LMG is an

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

internationally recognised culture collection which has the status of an International Depository Authority under the Budapest Treaty. In the LMG, cultures can be deposited in a restricted-access collection for safe deposit or for patent purposes. Data on the identification and characterisation of *B. longum* subsp. *infantis* THT 010201 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and in the accompanying references (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *B. longum* subsp. *infantis* THT 010201, is sufficiently characterised.

1.3. *Bifidobacterium longum* subsp. *longum* THT 010301 (ID 969, 970)

The food constituent that is the subject of the proposed health claims is *Bifidobacterium longum* subsp. *longum* THT 010301.

For *B. longum* subsp. *longum* THT 010301, a culture collection number from the Belgian BCCM/LMG, LMG 26652, was provided. Data on the identification and characterisation of *B. longum* subsp. *longum* THT 010301 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis, AFLP) methods, were provided in the applications for further assessment and in the accompanying references (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *B. longum* subsp. *longum* THT 010301, is sufficiently characterised.

1.4. *Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501 (ID 971, 972)

The food constituent that is the subject of the proposed health claims is *Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501.

The strain *B. pseudolongum* subsp. *pseudolongum* THT 010501 is the trade name for *B. pseudolongum* subsp. *pseudolongum* LMG 11571, which is the type strain of *B. pseudolongum* subsp. *pseudolongum*. Culture collection numbers from different internationally recognised culture collections (e.g. LMG 11571, ATCC 25526, DSM 20099) were provided. Data on the identification and characterisation of *B. pseudolongum* subsp. *pseudolongum* THT 010501 at species and strain level, by using different genotypic (16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, Hsp60 sequence analysis, Rep-PCR, MLST) methods, were provided (Jian et al., 2001; Leblond-Bourget et al., 1996; Masco et al., 2003; Ventura et al., 2006).

The Panel considers that the food constituent that is the subject of the proposed health claims, *B. pseudolongum* subsp. *pseudolongum* THT 010501, is sufficiently characterised.

1.5. *Lactobacillus casei* THT 030401 (ID 975, 976)

The food constituent that is the subject of the proposed health claims is *Lactobacillus casei* THT 030401.

The strain *L. casei* THT 030401 is the trade name for *L. casei* LMG 6904, which is the type strain of *L. casei*. Culture collection numbers from different internationally recognised culture collections (e.g. LMG 6904, ATCC 393, DSM 20011) were provided. Data on the identification and characterisation of *L. casei* THT 030401 at species and strain level, by using different phenotypic (carbohydrate fermentation profile and PFGE) and genotypic (DNA-DNA hybridisation, 16S/23S rRNA intergenic spacer region sequence analysis, recombinase A and elongation factor *tuf* gene sequence analyses, species-specific PCR and RAPD) methods, were provided (Chavagnat et al., 2002; Dicks et al., 1996; Felis et al., 2001; Song et al., 2000; Wayne, 1994).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. casei* THT 030401, is sufficiently characterised.

1.6. *Lactobacillus gasseri* THT 031301 (ID 983, 984)

The food constituent that is the subject of the proposed health claims is *Lactobacillus gasseri* THT 031301.

For *L. gasseri* THT 031301, a culture collection number from the BCCM/LMG, LMG 26661, was provided. Data on the identification and characterisation of *L. gasseri* THT 031301 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and in the accompanying references (BCCM/LMG, 2011b, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. gasseri* THT 031301, is sufficiently characterised.

1.7. *Lactobacillus helveticus* THT 031102 (ID 985, 986)

The food constituent that is the subject of the proposed health claims is *Lactobacillus helveticus* THT 031102.

For *L. helveticus* THT 031102, a culture collection number from the BCCM/LMG, LMG 26307, was provided. Data on the identification and characterisation of *L. helveticus* THT 031102 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and in the accompanying references (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. helveticus* THT 031102, is sufficiently characterised.

1.8. *Lactobacillus plantarum* THT 030701 (ID 994, 995)

The food constituent that is the subject of the proposed health claims is *Lactobacillus plantarum* THT 030701.

For *L. plantarum* THT 030701, a culture collection number from the BCCM/LMG, LMG 26654, was provided. Data on the identification and characterisation of *L. plantarum* THT 030701 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and in the accompanying references (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. plantarum* THT 030701, is sufficiently characterised.

1.9. *Lactobacillus plantarum* THT 030707 (ID 996, 997)

The food constituent that is the subject of the proposed health claims is *Lactobacillus plantarum* THT 030707.

For *L. plantarum* THT 030707, a culture collection number from the BCCM/LMG, LMG 26655, was provided. Data on the identification and characterisation of *L. plantarum* THT 030707 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and accompanying references (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. plantarum* THT 030707, is sufficiently characterised.

1.10. *Lactobacillus reuteri* THT 030802 (ID 998, 999)

The food constituent that is the subject of the proposed health claims is *Lactobacillus reuteri* THT 030802.

The strain *L. reuteri* THT 030802 is the trade name for *L. reuteri* LMG 9213, which is the type strain of *L. reuteri*. Culture collection numbers from different internationally recognised culture collections (e.g. LMG 9213, ATCC 23272, DSM 20016) were provided. Data on the identification and characterisation of *L. reuteri* THT 030802 at species and strain level, by using different phenotypic (carbohydrate fermentation profiles) and genotypic (16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, elongation factor *tuf* gene sequence analysis, species-specific PCR, REA, Rep-PCR and RAPD) methods, were provided (Chavagnat et al., 2002; Johansson et al., 1995; Kostinek et al., 2005; Kwon et al., 2004; Song et al., 2000; Yeung et al., 2002).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. reuteri* THT 030802, is sufficiently characterised.

1.11. *Lactobacillus salivarius* THT 031001 (ID 1006, 1007)

The food constituent that is the subject of the proposed health claims is *Lactobacillus salivarius* THT 031001.

The strain *L. salivarius* THT 031001 is the trade name for *L. salivarius* LMG 9477, which is the type strain of *L. salivarius*. Culture collection numbers from different internationally recognised culture collections (e.g. LMG 9477, DSM 20555) were provided. Data on the identification and characterisation of *L. salivarius* THT 031001 at species and strain level, by using different phenotypic (carbohydrate fermentation profiles) and genotypic (16S rRNA gene sequence analysis, 16S/23S intergenic spacer region sequence analysis, chaperoin groEL gene sequence analyses, PFGE) methods, were provided (Li et al., 2006; Rogosa et al., 1953; Takizawa et al., 1994).

The Panel considers that the food constituent that is the subject of the proposed health claims, *L. salivarius* THT 031001, is sufficiently characterised.

1.12. *Streptococcus thermophilus* THT 070102 (ID 1014, 1015)

The food constituent that is the subject of the proposed health claims is *Streptococcus thermophilus* THT 070102.

For *S. thermophilus* THT 070102, a culture collection number from the BCCM/LMG, LMG 26656, was provided. Data on the identification and characterisation of *S. thermophilus* THT 070102 at species and strain level, by using different phenotypic (cell morphology, enzymatic activities) and genotypic (16S rRNA gene sequence analysis and AFLP) methods, were provided in the applications for further assessment and in the references provided (BCCM/LMG, 2011a, unpublished).

The Panel considers that the food constituent that is the subject of the proposed health claims, *S. thermophilus* THT 070102, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

The claimed effects, which are proposed for further assessment, are: “The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by

several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients”, and “The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria improve the intestinal transit, especially by their participation in mobility intestinal. In more, they participate to the degradation of some indigestible substances and their absorption by the bowel.” The proposed target population is the general population.

The Panel notes that the claimed effect “contribute to the secretion and absorption of nutrients” is not sufficiently defined, and from the references provided it was not possible to establish for which nutrients an improved digestion and absorption is claimed.

The Panel assumes that the claimed effect “degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids” refers to changes in short chain fatty acid (SCFA) and lactic acid production. The Panel considers that changes in SCFA and lactic acid production in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome.

The Panel assumes that the claimed effects “they participate in mobility intestinal” and “improve the intestinal transit” refer to changes in bowel function. The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.

2.2. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

The claimed effect, which is proposed for further assessment, is: “The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances”. The proposed target population is the general population.

The Panel assumes that the claimed effect refers to a decrease in potentially pathogenic gastro-intestinal microorganisms. The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

2.3. Stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015)

The claimed effect, which is proposed for further assessment, is: “A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds”. The proposed target population is the general population.

The Panel notes that the claimed effect “modulation of the natural defences” is not sufficiently defined, and assumes that the claimed effect relates to the stimulation of various immunological responses. The Panel notes that stimulation of various immunological responses is not a beneficial physiological effect *per se* but needs to be linked to a beneficial physiological or clinical outcome.

No human studies which investigated the effect of the food constituent on any aspect of the immune system were provided in relation to any of the claims evaluated in this section.

Most of the references provided were on strains or combination of strains other than those which are the subject of the claims.

For ID 972, one *in vitro* study on the specific strain that is the subject of the claim, which investigated a health outcome (i.e. inhibitory effect of the strain on the adhesion of *Escherichia coli* O157:H7 to a

human epithelial cell line) (Gagnon et al., 2004) unrelated to the claimed effect evaluated in this section, was provided.

For ID 976, one study in animals which investigated the effects of the specific strain that is the subject of the claim on antibody production (IgG and IgM) after oral immunisation with recombinant tetanus toxin fragment C (Plant and Conway, 2002), and one *in vitro* study on the activation pattern of dendritic cells and the impact on T cell-dependent cytokine production from healthy and allergic donors (Ratajczak et al., 2007), were provided.

For ID 999, one *in vitro* study which investigated the effect of the specific strain that is the subject of the claim on the induction of cytokine secretion from splenic mononuclear cells isolated from mice (Matsuguchi et al., 2003) was provided.

The Panel considers that the evidence provided does not establish that stimulation of these immunological responses is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents, which are the subject of the claims evaluated in this section, and a beneficial physiological effect related to stimulation of immunological responses.

3. Scientific substantiation of the claimed effect

3.1. Changes in bowel function (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

Most of the references provided in relation to these claims were on bacterial strains or combinations of strains other than those which are the subject of the claims, or on strains in combination with other substances or on microorganisms for which information on the genus only was given. Narrative reviews on the survival of bacterial strains through the stomach and small intestine, on the isolation and selection of bacterial strains, and on the potential use of recombinant dietary lactic acid bacteria for the production of oral vaccines, which were unrelated to the claim, were also provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human intervention study on detection of the bacterial strain in faeces (Duez et al., 2000); animal or *in vitro* studies on induction of cytokine expression (Matsuguchi et al., 2003), inhibition of *Escherichia coli* urinary tract infections (Asahara et al., 2001), inhibition of *Escherichia coli* O157:H7 adhesion to human epithelial cells (Gagnon et al., 2004), protection against *Listeria monocytogenes* infection (Sato, 1984)); and/or animal and *in vitro* studies which addressed the potential use of a recombinant bacterial strain as carrier of proteins of immunological interest to intestinal mucosa mainly for the production of oral vaccines (Araujo Aires et al., 2006; Hazebrouck et al., 2006; Oliveira et al., 2006; Pant et al., 2006); and/or *in vitro* studies on the properties of the bacterial strains (e.g. survival capacity, growth at different temperatures and pH levels, viability in simulated gastro-intestinal, bile or pancreatic conditions; adhesion to human epithelial cells or to mucus from pig small intestine) (Crittenden et al., 2001; Crociani et al., 1995; Gagnon et al., 2004; Jonsson et al., 2001; Matsumoto et al., 2004; Matto et al., 2004; McMaster et al., 2005; Miyoshi et al., 2006; Todoriki et al., 2001) were also provided. The Panel notes that these studies did not address outcome measures related to the claimed effect, and considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and changes in bowel function.

3.2. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

Most of the references provided in relation to these claims were on bacterial strains or combinations of strains other than those which are the subject of the claims, or on strains in combination with other substances. Narrative reviews on the survival of bacterial strains through the stomach and small intestine, on the isolation and selection of bacterial strains, and on the potential use of recombinant dietary lactic acid bacteria for the production of oral vaccines, which were unrelated to the claim, were also provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Animal studies on induction of cytokine expression (Matsuguchi et al., 2003), on inhibition of *Escherichia coli* urinary tract infections (Asahara et al., 2001), and/or *in vitro* studies on the properties of the bacterial strains (i.e. survival capacity, growth at different temperatures and pH levels, viability in simulated gastro-intestinal, bile or pancreatic conditions; adhesion to human epithelial cells or to mucus from pig small intestine) (Crittenden et al., 2001; Crociani et al., 1995; Gagnon et al., 2004; Jonsson et al., 2001; Matsumoto et al., 2004; Matto et al., 2004; McMaster et al., 2005; Miyoshi et al., 2006; Todoriki et al., 2001), were also provided. *In vitro* and *in vivo* studies in animals which addressed the potential use of recombinant bacterial strains as carriers of proteins of immunological interest to intestinal mucosa mainly for the production of oral vaccines (Araujo Aires et al., 2006; Hazebrouck et al., 2006; Oliveira et al., 2006; Pant et al., 2006) were provided for ID 975. The Panel notes that these studies did not address outcome measures related to the claimed effect, and considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel notes that no human studies were provided from which conclusions could be drawn for the scientific substantiation of the claims evaluated in this section.

For ID 971, an *in vitro* study investigated the inhibition of *Escherichia coli* O157:H7 adhesion to a human epithelial cell line in the presence of the bacterial strain that is the subject of the claim (Gagnon et al., 2004). For ID 975, a study in animals investigated the protective activity of the bacterial strain that is the subject of the claim against *Listeria monocytogenes* infection (Sato, 1984). The Panel considers that in the absence of evidence for an effect on decreasing potentially pathogenic gastro-intestinal microorganisms in humans, evidence provided in animal and *in vitro* studies cannot be used alone for the scientific substantiation of a claim on decreasing potentially pathogenic gastro-intestinal microorganisms.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims evaluated in this section and decreasing potentially pathogenic gastro-intestinal microorganisms.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The following food constituents are sufficiently characterised:
 - Bifidobacterium animalis* subsp. *lactis* THT 010801 (ID 960, 961, 962),
 - Bifidobacterium longum* subsp. *infantis* THT 010201 (ID 967, 968),
 - Bifidobacterium longum* subsp. *longum* THT 010301 (ID 969, 970),
 - Bifidobacterium pseudolongum* subsp. *pseudolongum* THT 010501 (ID 971, 972),
 - Lactobacillus casei* THT 030401 (ID 975, 976),
 - Lactobacillus gasseri* THT 031301 (ID 983, 984),
 - Lactobacillus helveticus* THT 031102 (ID 985, 986),

Lactobacillus plantarum THT 030701 (ID 994, 995),
Lactobacillus plantarum THT 030707 (ID 996, 997),
Lactobacillus reuteri THT 030802 (ID 998, 999),
Lactobacillus salivarius THT 031001 (ID 1006, 1007),
Streptococcus thermophilus THT 070102 (ID 1014, 1015).

Changes in bowel function, and digestion and absorption of nutrients (ID 960, 961, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

- The claimed effects proposed for further assessment relate to “contribute to the secretion and absorption of nutrients”, “degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids”, “they participate in mobility intestinal” and “improve the intestinal transit”. The claimed effect “contribute to the secretion and absorption of nutrients” is not sufficiently defined and it was not possible to establish for which nutrients an improved digestion and absorption is claimed. The claimed effect “degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids” is assumed to refer to changes in short chain fatty acid (SCFA) and lactic acid production. Changes in SCFA and lactic acid production in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. The claimed effects “they participate in mobility intestinal” and “improve the intestinal transit” are assumed to refer to changes in bowel function. The proposed target population is the general population. Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.
- A cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and changes in bowel function.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 960, 967, 969, 971, 975, 983, 985, 994, 996, 998, 1006, 1014)

- The claimed effect proposed for further assessment relates to a decrease in potentially pathogenic gastro-intestinal microorganisms. The proposed target population is the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food constituents which are the subject of the claims and decreasing potentially pathogenic gastro-intestinal microorganisms.

Stimulation of immunological responses (ID 962, 968, 970, 972, 976, 984, 986, 995, 997, 999, 1007, 1015)

- The claimed effect proposed for further assessment relates to the stimulation of various immunological responses. The proposed target population is the general population. The evidence provided did not establish that stimulation of immunological responses is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food constituents, which are the subject of the claims, and a beneficial physiological effect related to stimulation of immunological responses.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00133, EFSA-Q-2012-00134, EFSA-Q-2012-00135, EFSA-Q-2012-00136, EFSA-Q-2012-00137, EFSA-Q-2012-00138, EFSA-Q-2012-00139, EFSA-Q-2012-00140, EFSA-Q-2012-00141, EFSA-Q-2012-00142, EFSA-Q-2012-00143, EFSA-Q-2012-00144, EFSA-Q-2012-00145, EFSA-Q-2012-00146, EFSA-Q-2012-00147, EFSA-Q-2012-00148, EFSA-Q-2012-00149, EFSA-Q-2012-00150, EFSA-Q-2012-00151, EFSA-Q-2012-00152, EFSA-Q-2012-00153, EFSA-Q-2012-00154, EFSA-Q-2012-00155, EFSA-Q-2012-00158, EFSA-Q-2012-00159). The scientific substantiation is based on the information provided by the competent Authority of Belgium for the further assessment of this claim (available at: <http://www.efsa.europa.eu/en/topics/topic/article13.htm>).

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁵ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁶

Foods are commonly involved in many different functions⁷ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

⁵ OJ L12, 18/01/2007

⁶ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁷ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B**EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Health claims related to various microorganisms, including conditions of use, as proposed in the framework of further assessment.

ID	Food or Food constituent	Health Relationship	Proposed wording
960	<i>Bifidobacterium animalis subsp. lactis</i> THT 010801	The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients. The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
961	<i>Bifidobacterium animalis subsp. lactis</i> THT 010801	The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria improve the intestinal transit, especially by their participation in mobility intestinal. In more, they participate to the degradation of some indigestible substances and their absorption by the bowel	Helps to improve intestinal transit Helps to reduce natural digestion Helps to regulate intestinal flora Promotes intestinal comfort
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included		
ID	Food or Food constituent	Health Relationship	Proposed wording
962	<i>Bifidobacterium animalis subsp. lactis</i> THT 010801	A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.	Helps to strengthen natural defences Stimulates immune system Strengthens resistance of organism
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		

ID	Food or Food constituent	Health Relationship	Proposed wording
967	<i>Bifidobacterium longum</i> subsp. <i>infantis</i> THT 010201	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
	<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
968	<i>Bifidobacterium longum</i> subsp. <i>infantis</i> THT 010201	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>
	<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
969	<i>Bifidobacterium longum</i> subsp. <i>longum</i> THT 010301	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
	<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>		

ID	Food or Food constituent	Health Relationship	Proposed wording
970	<i>Bifidobacterium longum subsp. longum</i> THT 010301	A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.	Helps to strengthen natural defences Stimulates immune system Strengthens resistance of organism
	Conditions of use At least 10 E+8 CFU/day		
ID	Food or Food constituent	Health Relationship	Proposed wording
971	<i>Bifidobacterium pseudolongum subsp. pseudolongum</i> THT 010501	The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients. The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
972	<i>Bifidobacterium pseudolongum subsp. pseudolongum</i> THT 010501	A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.	Helps to strengthen natural defences Stimulates immune system Strengthens resistance of organism
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
975	<i>Lactobacillus casei</i> THT 030401	The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and	Maintains/restores the balance of intestinal flora Promotes intestinal comfort

		<p>volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances</p>	<p>Strengthens resistance of organism</p> <p>Improves digestive health.</p>
<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
976	<i>Lactobacillus casei</i> THT 030401	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>
<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
983	<i>Lactobacillus gasseri</i> THT 031301	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
<p>Conditions of use</p> <p>At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
984	<i>Lactobacillus gasseri</i> THT 031301	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>

		defence by their presence or by production of some compounds.	
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
985	<i>Lactobacillus helveticus</i> THT 031102	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
986	<i>Lactobacillus helveticus</i> THT 031102	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.</p>	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
994	<i>Lactobacillus plantarum</i> THT 030701	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by</p>	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health

		competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.	
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
995	<i>Lactobacillus plantarum</i> THT 030701	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
996	<i>Lactobacillus plantarum</i> THT 030707	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
997	<i>Lactobacillus plantarum</i> THT 030707	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>
Conditions of use			

At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
998	<i>Lactobacillus reuteri</i> THT 030802	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
999	<i>Lactobacillus reuteri</i> THT 030802	<p>A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells.</p> <p>The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.</p>	<p>Helps to strengthen natural defences</p> <p>Stimulates immune system</p> <p>Strengthens resistance of organism</p>
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1006	<i>Lactobacillus salivarius</i> THT 031001	<p>The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients.</p> <p>The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances.</p>	<p>Maintains/restores the balance of intestinal flora</p> <p>Promotes intestinal comfort</p> <p>Strengthens resistance of organism</p> <p>Improves digestive health</p>
	Conditions of use		

- At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.			
ID	Food or Food constituent	Health Relationship	Proposed wording
1007	<i>Lactobacillus salivarius</i> THT 031001	A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.	Helps to strengthen natural defences Stimulates immune system Strengthens resistance of organism
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1014	<i>Streptococcus thermophilus</i> THT 070102	The micro-organisms are known, for a long time, for their intestinal impact. Indeed, the bacteria promote the digestive health by several ways. Among other thing, they degrade indigestible substances (sugars, etc.) into lactic acid and volatile fatty acids. They participate in mobility intestinal. They contribute to the secretion and absorption of nutrients. The bacteria modulate also intestinal flora. They have a protective function by competitive inhibition on pathogen (competing for growth). They inhibit too the adhesion of these pathogens by site occupation and by production of anti-microbial substances	Maintains/restores the balance of intestinal flora Promotes intestinal comfort Strengthens resistance of organism Improves digestive health
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1015	<i>Streptococcus thermophilus</i> THT 070102	A lot of study is shown an impact of bacteria on immune system. They improve, for example, the immune function by induction of various molecules and by modification of activity of some cells. The bacteria modulate also the natural defences. Indeed, they stimulate the natural defence by their presence or by production of some compounds.	Helps to strengthen natural defences Stimulates immune system Strengthens resistance of organism
	Conditions of use At least 10 E+8 CFU/day. The target population is the normal population, child and sick person not included.		

GLOSSARY AND ABBREVIATIONS

AFLP	Amplified fragment length polymorphism
ARDRA	Amplified rDNA restriction analysis
ATCC	American Type Culture Collection
BCCM/LMG	Belgian Co-ordinated Collections of Microorganisms/Laboratorium voor Microbiologie, Universiteit Gent
DNA	Deoxyribonucleic acid
MLST	Multi-locus sequence typing
PAGE	Polyacrylamide gel electrophoresis.
PCR	Polymerase chain reaction
PFGE	Pulsed field gel electrophoresis
RAPD	Randomly amplified polymorphic DNA.
REA	Chromosomal DNA restriction analysis.
Rep-PCR	Repetitive extragenomic palindromic – PCR
RNA	Ribonucleic acid
SCFA	Short chain fatty acid